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Glaxo Smith Kline  
c/o The Nath Law Group  
112 South West St.  
Alexandria, VA 22314-2825

EXAMINER
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CHANNAVAJJALA, LAKSHMI SARADA

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* KARL F. POPP

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Appeal 2009-010010  
Application 10/617,191  
Technology Center 1600

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Decided: March 3, 2010

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Before DEMETRA J. MILLS, ERIC GRIMES, and STEPHEN WALSH,  
*Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of making a topical composition, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification discloses a topical composition for treating skin disorders or conditions (Spec. 2). The composition is made by combining

a benzoyl peroxide dispersion and a clindamycin solution (*id.* at 8-9), and producing a composition having a viscosity lower than the viscosity of the benzoyl peroxide dispersion (*id.* at 8).

Claims 26-31 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 26 is representative and reads as follows:

26. A process for preparing a storage-stable topical composition for treating a skin disorder or condition, which comprises the steps of:

- a) forming at a temperature of about 15 to about 25 °C a benzoyl peroxide intermediate dispersion having a viscosity of about 60,000 to about 250,000 centipoises sufficient to yield a composition which contains between about 2.25% and about 12.5% by weight benzoyl peroxide in the final product;
- b) forming at a temperature of about 15 to about 25 °C a clindamycin intermediate solution sufficient to yield a composition which contains between about 0.5% and about 1.5% by weight clindamycin active in the final product; and
- c) mixing said benzoyl peroxide intermediate dispersion and said clindamycin intermediate solution under conditions sufficient to yield a benzoyl peroxide and clindamycin mixture having final pH of between about 4.5 to about 5.0,

wherein said mixture has a viscosity lower than the viscosity of the benzoyl peroxide intermediate dispersion, wherein the viscosity of the mixture is of about 50,000 to about 200,000 centipoises, and wherein said composition comprises sufficient inactive ingredients to provide storage stability and effectiveness for a treatment period.

### *Issue*

The Examiner has rejected claims 26-31 under 35 U.S.C. § 103(a) as obvious in view of Baroody<sup>1</sup> (Ans. 3). The Examiner finds that Baroody discloses a storage-stable composition made by mixing clindamycin and

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<sup>1</sup> Baroody et al., U.S. Patent 6,117,843, issued Sept. 12, 2000.

benzoyl peroxide (*id.*) with viscosities overlapping those recited in claim 26 (*id.* at 4-5) but “does not teach that the final viscosity is lower than the viscosity of benzoyl peroxide dispersion” (*id.* at 4). The Examiner concludes that the claimed process nonetheless would have been obvious because Appellant has not shown that the relative viscosities are critical to the stability of the composition and “a skilled artisan would have been able to adjust the initial viscosity of benzoyl peroxide in the claimed range . . . with an expectation to achieve a composition of an appropriate viscosity that is stable for long periods of time” (*id.* at 6).

Appellant contends that Baroody emphasizes that a lower-viscosity benzoyl peroxide dispersion provides the advantage of easier mixing and therefore would not have suggested using a higher-viscosity benzoyl peroxide dispersion, as recited in claim 26 (Appeal Br. 15-25). Appellant also contends that the claimed process provides unexpected results and advantages compared to Baroody’s process (*id.* at 25-29).

The issues presented are:

Does the evidence of record support the Examiner’s position that it would have been obvious to modify Baroody’s process by using a benzoyl peroxide composition with a viscosity higher than that of the final composition?,

and

If so, has Appellant provided evidence of unexpected results that outweighs the evidence in favor of obviousness?

*Findings of Fact*

1. Baroody discloses acne treatment compositions comprising 1% to 20% by weight benzoyl peroxide and 0.2% to 4% by weight clindamycin (Baroody, col. 2, ll. 39-49).

2. Baroody discloses that “the topical compositions are prepared by combining or admixing an aqueous gel suspension of benzoyl peroxide with an aqueous solution of a clindamycin salt or ester” (*id.* at col. 2, ll. 61-64).

3. Baroody discloses that the clindamycin solution has a pH “within a range of 3.5 to 7, preferably within a range of 6 to 6.5” (*id.* at col. 5, ll. 31-32).

4. Baroody discloses that the benzoyl peroxide composition has “a pH in the range from 3.5 to 7.0, preferably in the range from 4.0 to 5.0” (*id.* at col. 5, l. 66 to col. 6, l. 1).

5. Baroody discloses that “[b]y combining preselected amounts of the two components, the pH of the combination will be below 7 and the combination will remain stable for several months after admixture at room temperature” (*id.* at col. 3, ll. 9-13).

6. Baroody discloses that the “aqueous suspension of benzoyl peroxide is stored at a pH from 3.5 to 7.0, typically with a gelling agent which has a relatively low viscosity at the storage pH” (*id.* at col. 3, ll. 4-9).

7. Baroody discloses that

[b]y properly selecting the nature of the gelling agent and the pH of the benzoyl peroxide component, the benzoyl peroxide component itself may be maintained at a relatively low viscosity while the final topical composition (which is at a different pH) will have a relatively higher viscosity. In this way, mixing of the two components to form the topical composition is facilitated . . . while the final topical

composition can still possess the desired higher viscosity, gel consistency.

(*Id.* at col. 5, ll. 46-57.)

8. Baroody discloses that “[p]referably, the viscosity of the benzoyl peroxide . . . component will be below about  $9 \times 10^4$  cp, usually being in the range from  $5 \times 10^4$  cp to  $9 \times 10^4$  cp . . . while the viscosity of the final topical composition product will be in the range from  $7 \times 10^4$  cp to  $12 \times 10^4$  cp, more preferably being in the range from  $8 \times 10^4$  cp to  $10 \times 10^4$  cp” (*id.* at col. 5, ll. 58-64).

9. Baroody discloses that “[b]y maintaining the compositions at a pH below 7, the tendency of benzoyl peroxide to oxidize and degrade clindamycin is largely overcome and the product remains stable during storage at room temperature for extended periods, typically several months or longer” (*id.* at col. 2, ll. 49-54).

10. The Specification states that “[b]y maintaining the compositions at the present specific pH, the tendency of benzoyl peroxide to oxidize and degrade clindamycin is largely overcome and the product remains stable during storage at room temperature for extended periods, typically several months or longer” (Spec. 34:17 to 35:3).

### *Principles of Law*

“If a person of ordinary skill can implement a predictable variation [of a known work], § 103 likely bars its patentability.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007)

“Under 35 U.S.C. § 103, a reference must be considered not only for what it expressly teaches, but also for what it fairly suggests. . . . [W]e reiterate that ‘all disclosures of the prior art, including unpreferred

embodiments, must be considered' in determining obviousness." *In re Burckel*, 592 F.2d 1175, 1179 (CCPA 1979).

"[I]n general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

"[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art." *In re Baxter-Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991).

### *Analysis*

Baroody discloses a method of making a topical composition by mixing separate benzoyl peroxide and clindamycin compositions. Baroody discloses ranges for the concentrations of the compositions, the viscosities of the benzoyl peroxide and final compositions, and the pH of the final composition that overlap the ranges recited in claim 26. Overlapping ranges typically show a prima facie case of obviousness. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003).

Appellant does not argue that the claimed process is distinguished from the process taught by Baroody by the concentrations, viscosities, or pH range recited in the claim. Nor does Appellant argue that mixing at room temperature, as recited in claim 26, would not have been obvious to a skilled worker.

Rather, Appellant argues that the claimed process would not have been obvious based on Baroody because the claimed process requires the benzoyl peroxide dispersion to have a *higher* viscosity than the final composition, and Baroody teaches that a benzoyl peroxide dispersion with a

*lower* viscosity than the final composition facilitates mixing. Appellant argues that this teaching would not have led a skilled worker to modify Baroody's method in the manner required by the claims (Appeal Br. 16) and in fact would have taught away from doing so because that would have been expected to make the mixing process more difficult (*id.* at 18-20). Along the same line, Appellant argues that Baroody's teaching shows that the claimed process proceeds in a direction contrary to the generally accepted wisdom, supporting the nonobviousness of the claims (*id.* at 22-25, citing *In re Hedges*, 783 F.2d 1038 (Fed. Cir. 1986)).

These arguments do not persuade us that the Examiner's rejection should be reversed. It is true that Baroody points out that starting with a benzoyl peroxide composition with a lower viscosity than the final composition facilitates mixing of the benzoyl peroxide and clindamycin compositions. A skilled worker would therefore expect that a benzoyl peroxide composition with a higher viscosity than the final composition would require more effort to mix with a clindamycin composition.

Baroody, however, does not disclose or suggest that an acceptable clindamycin/benzoyl peroxide composition cannot be made using a benzoyl peroxide composition with a higher viscosity than the final composition. Baroody therefore does not teach away from the claimed process, because it does not teach that modifying the method as required by the claims would make it unusable. Baroody merely discloses that using a higher-viscosity benzoyl peroxide composition is a non-preferred embodiment of its method.

A person of ordinary skill in the art would expect, based on Baroody, that practicing its method using a benzoyl peroxide composition with a higher viscosity than the final composition would also produce an acceptable



final product, even if the mixing process was more difficult. “If a person of ordinary skill can implement a predictable variation [of a known work], § 103 likely bars its patentability.” *KSR*, 550 U.S. at 417. A non-preferred embodiment of a disclosed method is a predictable variation of that method, and therefore obvious to those of ordinary skill in the art.

We do not agree that *In re Hedges*, 783 F.2d 1038 (Fed. Cir. 1986), supports the nonobviousness of the claimed process. In *Hedges*, the claimed invention was “the reaction of diphenyl sulfone, at a temperature above its melting point of 127°C, with liquid or gaseous sulfur trioxide in the absence of water or a solvent.” *Id.* at 1039. The reference relied on for obviousness taught carrying out the reaction at a much lower temperature, *id.*, but the PTO took the position that “determining the optimum temperature is a matter of ‘routine experimentation.’” *Id.* at 1040.

The inventor pointed to prior art that showed that similar reactions either led to charring and decomposition, or required the presence of solvent, at high temperatures. *Id.* The court concluded that “the references all suggest[ed] that lower temperatures of reaction are preferable. No reference suggests that diphenyl sulfone may advantageously be reacted in the molten state with sulfur trioxide. The data provided by Hedges show significant advantages of the claimed invention.” *Id.* at 1041. Based on all of the evidence, the court held that the PTO had not shown the claimed method to be obvious. *Id.*

Thus, in *Hedges*, the evidence showed that those skilled in the art would have expected that the claimed reaction either would not have proceeded, because a solvent was required at high temperatures, or would have led to charring and decomposition of the product. In contrast, the

evidence of record in this case only shows that those skilled in the art would have expected that Baroody's composition would have required more effort to mix if the benzoyl peroxide composition had a higher viscosity, not that it could not have been mixed or would have produced an unacceptable product.

The *Hedges* court did not hold that the claimed reaction conditions were nonobvious merely because they would have slowed the rate of the reaction or would have required an additional purification step, factors that would be similar to the added mixing suggested by Baroody. On these facts, therefore, *Hedges* does not require reversal of the Examiner's rejection.

Appellant also argues that Baroody "would predict the inability to prepare a storage stable topical composition due to the difficulty of mixing the various components" (Appeal Br. 16). This argument is not persuasive, because Appellant has pointed to nothing in Baroody that states that its components could not be adequately mixed if the benzoyl peroxide composition had a higher viscosity than the final composition.

Finally, Appellant argues that the claimed process provides unexpected results compared to Baroody's, in that the claimed process "provides compositions that are easier to mix together, contain less degradates, and have a greater degree of uniformity than those compositions previously known in the art, including the Baroody et al. composition" (Appeal Br. 26-27). Appellant also argues that the claimed process provides compositions that are more storage-stable than Baroody's (*id.* at 27-28) and does not require the composition to be compounded at the time of dispensing (*id.* at 28).

This argument is also unpersuasive, because Appellant has not pointed to evidence in the record showing a comparison of the claimed process to that of Baroody, which differs from the claims only in the relative viscosity of the benzoyl peroxide and final compositions. Appellant has not provided evidence, for example, to support the assertion that the claimed process provides compositions that are easier to mix and have greater uniformity than the composition resulting from Baroody's process. *See In re Hoeschele*, 406 F.2d 1403, 1406 (CCPA 1969) (“[A]n arguable difference where comparative evidence is clearly needed is not convincing.”).

The other properties that are asserted to be unexpected are all aspects of storage stability – greater storage stability results in less degradates and allows mixing in a production facility rather than at the time of dispensing. Both Baroody and the instant Specification provide evidence, however, that storage stability is a result of the pH of the final composition, not the viscosity of the benzoyl peroxide composition (FFs 9, 10). Appellant has not provided comparative evidence to show that the pH range recited in the claims (pH 4.5 – 5.0) provides unexpectedly improved storage stability compared to the pH ranges disclosed by Baroody.

### *Conclusion of Law*

The evidence of record supports the Examiner's position that it would have been obvious to modify Baroody's process by using a benzoyl peroxide composition with a viscosity higher than that of the final composition. And Appellant has not provided evidence of unexpected results that outweighs the evidence in favor of obviousness.

SUMMARY

We affirm the rejection of claims 26-31 under 35 U.S.C. § 103(a) as obvious in view of Barody.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

lp

GLAXO SMITH KLINE  
C/O THE NATH LAW GROUP  
112 SOUTH WEST ST.  
ALEXANDRIA VA 22314-2825